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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

August 18, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 31

Raymond F. Geske
Owner/President
Tri-County Dairy Supply, Inc.
4107 Highway 51 North
Janesville, Wisconsin 53545

Dear Mr. Geske:

On May 13 and 28, 2003, investigators from the Food and Drug Administration conducted an inspection of your facility at 4107 Highway 51 North, Janesville, Wisconsin. During this inspection, the investigator obtained information about your firm's repackaging and distribution of teat dip. These teat dips are identified as Tri-Soft™ Pre & Post Sanitizing Teat Dip, Tri-Soft™ 110 Pre & Post Sanitizing Teat Dip, and Tri-Soft™ Plus Pre & Post Sanitizing Teat Dip.

These products are adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that teat dip is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practice (cGMP). These cGMPS have been defined as regulations in Title 21, Code of Federal Regulations, Part 211 (21 CFR 211).

The specific deficiencies noted in your firm's repackaging and distribution operation were noted on the Form FDA-483, Inspectional Observations, presented to you at the conclusion of the inspection. The deviations from the cGMP requirements include:

1. Failure to have and implement a Master Production and Control Record for each of the three teat dips as required by 21 CFR 211.186(a).

2. Failure to utilize Batch Production and Control Records for each batch of teat dip repackaged, as required by 21 CFR 211.188.

3. Failure to have implemented written procedures for production and process control designed to assure that the teat dip products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 CFR 211.100(a).

4. Failure to have appropriate laboratory determinations of satisfactory conformance to final specifications, as required by 21 CFR 211.165(a).

5. Failure to have and implement written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials, as required by 21 CFR 211.122(a).

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure or injunction.

This letter does not represent a comprehensive review of all of the products distributed by your firm. As owner, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TSW/ccl